CORRECTED VERSION

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- (71) Applicant (for all designated States except US): MERCK PATENT GMBH [DE/DE]; Frankfurter Strasse 250, 64293 Darmstadt (DE).
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- (74) Common Representative: MERCK PATENT GMBH; Frankfurter Strasse 250, 64293 Darmstadt (DE).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHYLENE UREA DERIVATIVES AS RAF-KINASE INHIBITORS

(57) Abstract: The present invention relates to methylene urea derivatives of formula (I), the use of the compounds of formula (I) as inhibitors of raf-kinase, the use of the compounds of formula (I) for the manufacture of a pharmaceutical composition and a method of treatment, comprising administering said pharmaceutical composition to a patient.



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- (72) Inventors; and
- (75) Inventors/Applicants (for US only): BUCHSTALLER, Hans-Peter [AT/DE]; Heinrichstrasse 54, 64331 Weiterstadt (DE). WIESNER, Matthias [DE/DE]; Beethovenring 10, 64342 Seeheim-Jugenheim (DE). SCHADT, Oliver [DE/DE]; Eschenstrasse 32, 63517 Rodenbach (DE). AMENDT, Christiane [DE/DE]; Barkhausstrasse 22, 64289 Darmstadt (DE). ZENKE, Frank [DE/DE]; Schulzengasse 7, 64291 Darmstadt (DE). SIRRENBERG, Christian [DE/DE]; Taunusstrasse 10, 64289 Darmstadt (DE). GRELL, Matthias [DE/DE]; Lindenweg 44, 64291 Darmstadt (DE). FINSINGER, Dirk [DE/DE]; Im Fiedlersee 5, 64291 Darmstadt (DE).

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- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C07D213/68 C07D213/75 C07D417/12 A61K31/44

C. DOCUMENTS CONSIDERED TO BE RELEVANT

C07D401/12 C07D413/12 A61K31/4427 A61P29/00

C07D409/12

Relevant to claim No.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 CO7D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data, BEILSTEIN Data, WPI Data

Citation of document, with indication, where appropriate, of the relevant passages

X	WO 01/38324 A (LOVELL PETER JO DAVID KENNETH (GB); SMITHKLINE	1-3,7-32	
Y	(G) 31 May 2001 (2001-05-31) see examples78-81 and claims 1	1-32	
X	WO 02/24679 A (SHIMADA MITSUYU AG (DE); ZIEGELBAUER KARL B (D Y) 28 March 2002 (2002-03-28)	1-3,7,8, 10-15, 17-23, 26-28, 30-32	
	see e.g. example 32-14 and cla 7, 9-15	ims 1-4, 6,	
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	1		l l
X Fu	orther documents are listed in the continuation of box C.	Patent family members are listed	lin annex.
° Special o	rither documents are listed in the continuation of box C. categories of cited documents: ment defining the general state of the art which is not sidered to be of particular relevance	Patent family members are listed "T" later document published after the interpretation or priority date and not in conflict with cited to understand the principle or time invention."	ternational filing date
° Special of A* documents on S*E* earlier	categories of cited documents: ment defining the general state of the art which is not sidered to be of particular relevance are document but published on or after the international g date	"T" later document published after the Initial or priority date and not in conflict with clied to understand the principle or timention "X" document of particular relevance; the cannot be considered novel or cannot b	ternational filing date In the application but It is application b
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° Special of Constant	categories of cited documents: ment defining the general state of the art which is not sidered to be of particular relevance or document but published on or after the international grate of the definition of the side of the stabilish the publication date of another tion or other special reason (as specified) ment referring to an oral disclosure, use, exhibition or are means ment published prior to the international filing date but	"T" later document published after the interpretation or priority date and not in conflict with cited to understand the principle or to invention "X" document of particular relevance; the cannot be considered novel or campinate or inventive step when the control of particular relevance; the	ternational filing date in the application but heory underlying the claimed invention of the considered to locument is taken alone claimed invention inventive step when the nore other such docu- ous to a person sidiled
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Special (*A* docur cons *E* earlie filling *L* docur whic citat *O* docur othe *P* docur later	categories of cited documents: ment defining the general state of the art which is not sidered to be of particular relevance or document but published on or after the international grate of the date of the dat	"T" later document published after the Interpretation of priority date and not in conflict with cited to understand the principle or to invention. "X" document of particular relevance; the cannot be considered novel or cannot have an inventive step when the control of particular relevance; the cannot be considered to involve an index of particular relevance; the cannot be considered to involve an index of the cannot be considered to involve an index of the cannot be considered to involve an index of the combination being obvious the art. "&" document member of the same pater.	ternational filing date In the application but theory underlying the claimed invention of be considered to locument is taken alone claimed invention inventive step when the more other such docu- tous to a person sidlled int family



	PCT/EP 03/11134					
C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT Category Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No.						
Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.					
WO 02/062750 A (SCHERING CORP) 15 August 2002 (2002-08-15)	1-3,7, 10-15, 17-23, 26-28, 30-32					
see compound CU on p. 25, compound III on p. 45 and compound 33 page 70; claims 1,2,30,33-37						
EP 0 839 803 A (SS PHARMACEUTICAL CO) 6 May 1998 (1998-05-06)	1-3,7, 10-15, 19,20, 22,23, 26-28, 30-32					
claims 1-3,5,6; examples 1-36						
DE 199 47 457 A (AVENTIS PHARMA GMBH) 5 April 2001 (2001-04-05)	1-3,7, 10-15, 19,23, 26-28, 30-32					
claims 1-3; examples 5A,5B						
WO 02/12210 A (BERNARDON JEAN MICHEL ;CLARY LAURENCE (FR); GALDERMA RES & DEV (FR) 14 February 2002 (2002-02-14)	1-3,7, 10-15, 17,19, 20, 26-28, 30-32					
claims 1,10,15,18; examples 9,10						
SMITH R A ET AL: "DISCOVERY OF HETEROCYCLIC UREAS AS A NEW CLASS OF RAF KINASE INHIBITORS: IDENTIFICATION OF A SECOND GENERATION LEAD BY A COMBINATORIAL CHEMISTRY APPROACH" BIOORGANIC & MEDICINAL CHEMISTRY LETTERS, OXFORD, GB, vol. 11, no. 20, 2001, pages 2775-2778, XP001118699 ISSN: 0960-894X see lead compound 89	1-32					
WO 02/062763 A (RIEDL BERND ;LOWINGER TIMOTHY B (JP); DUMAS JACQUES (US); RENICK J) 15 August 2002 (2002-08-15) tables 1-6, claims 1-33	1-32					
	Citation of document, with indication, where appropriate, of the relevant passages WO 02/062750 A (SCHERING CORP) 15 August 2002 (2002-08-15) see compound CU on p. 25, compound III on p. 45 and compound 33 page 70; claims 1,2,30,33-37 EP 0 839 803 A (SS PHARMACEUTICAL CO) 6 May 1998 (1998-05-06) claims 1-3,5,6; examples 1-36 DE 199 47 457 A (AVENTIS PHARMA GMBH) 5 April 2001 (2001-04-05) claims 1-3; examples 5A,5B WO 02/12210 A (BERNARDON JEAN MICHEL; CLARY LAURENCE (FR); GALDERMA RES & DEV (FR) 14 February 2002 (2002-02-14) claims 1,10,15,18; examples 9,10 SMITH R A ET AL: "DISCOVERY OF HETEROCYCLIC UREAS AS A NEW CLASS OF RAF KINASE INHIBITORS: IDENTIFICATION OF A SECOND GENERATION LEAD BY A COMBINATORIAL CHEMISTRY APPROACH" BIOORGANIC & MEDICINAL CHEMISTRY LETTERS, OXFORD, GB, vol. 11, no. 20, 2001, pages 2775-2778, XP001118699 ISSN: 0960-894X see lead compound 89 WO 02/062763 A (RIEDL BERND; LOWINGER TIMOTHY B (JP); DUMAS JACQUES (US); RENICK J) 15 August 2002 (2002-08-15) tables 1-6, claims 1-33					



0.10	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	101/21 03/11104
Category °		Relevant to claim No.
Х	US 4 057 636 A (PETERSEN HANS JORGEN) 8 November 1977 (1977-11-08)	1,2,7, 10-15, 19,23,
	see the 5 benzylderivatives of table A and examples 37 and 57, its production and pharmacological activity	26-28,31
X	US 5 441 984 A (HEATH, WILLIAM F., JR. ET AL) 15 August 1995 (1995-08-15)	1,2,7, 10-15, 19,23, 26-28,31
	see examples 6 and 10, its production and activity	
X,P	HOPKINS, THUTAM P. ET AL: "Solid-Phase Synthesis of Trisubsituted Guanidines" JOURNAL OF COMBINATORIAL CHEMISTRY, 4(2), 167-174 CODEN: JCCHFF; ISSN: 1520-4766, 2002, XP002289534 see compound with RN 409080-96-2 and its production	1-3, 30-32
X	WO 00/61561 A1 (SHIONOGI BIORESEARCH CORP., USA) 19 October 2000 (2000-10-19)	1,2,7, 10-15, 17,18, 21,22, 26-28, 30-32
	see inter alia many especially example 26, its production and activity	
X	WO 00/61559 A1 (SHIONOGI RESEARCH CORP., USA) 19 October 2000 (2000-10-19)	1-3,7, 10-15, 17,18, 21,22, 26-28
	see e.g. examples 14-16 and scheme on p.	
X	WO 95/18126 A1 (FUJISAWA PHARMACEUTICAL CO., LTD., JAPAN) 6 July 1995 (1995-07-06)	1,2,7, 10-15, 19,20, 22,23, 26-28
	see compound with CAS RN 168971-19-5	
X	WO 02/02534 A1 (ASTRAZENECA AB, SWED.; ASTRAZENECA UK LTD.) 10 January 2002 (2002-01-10)	1,2,7,8, 10-15, 17,18, 21,22, 26-28
	see examples 6, 16 and 31	



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Category °	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	- ·, · · · · · · · · · · · · · · · · · · 		
Calegory	Citation of document, with Indication, where appropriate, of the relevant passages		Relevant to claim No.	
X	WO 01/57008 A1 (BASF AKTIENGESELLSCHAFT, GERMANY) 9 August 2001 (2001-08-09) see e.g. inter alia examples 24 and 26-31		1,2,7,8, 10-15, 17,18, 20-22, 26-28,31	
	see e.g. inter alia examples 24 and 26-31 and in combination with scheme II		20-22, 26-28, 31	



INTERNATIONAL SEARCH REPORT

International application No. PCT/EP 03/11134

Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet) Box I This International Search Report has not been established in respect of certain daims under Article 17(2)(a) for the following reasons: Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely: 1-3, 7-32(part)Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically: see FURTHER INFORMATION sheet PCT/ISA/210 Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a). Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet) This International Searching Authority found multiple Inventions in this International application, as follows: see additional sheet As all required additional search fees were timely paid by the applicant, this international Search Report covers all searchable claims. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee. As only some of the required additional search fees were timely paid by the applicant, this international Search Report 3. covers only those claims for which fees were paid, specifically claims Nos.: No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: The additional search fees were accompanied by the applicant's protest. **Remark on Protest** No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-3, 7-32(part)

Present claims 1 to 3, 7 to 32 relate to an extremely large number of possible compounds, processes for their production, compositions and methods. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

Furthermore, the initial phase of the search revealed a very large number of documents relevant to the issue of novelty. So many documents were retrieved that it is impossible to determine which parts of the claim(s) may be said to define subject-matter for which protection might legitimately be sought (Article 6 PCT).

For these two reasons, a meaningful search over the whole breadth of the claims 1 to 3 and 7 to 32 is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely the search has been restricted to the compounds of claim 4 to 6 and the claims depending thereon, but only as far as as the specified compounds of claims 4, 5 and 6 are concerned.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

Information on patent family members

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